

**Tentative Agenda July 14, 2000**  
**Joint Meeting - Nonprescription Drugs Advisory Committee &**  
**Endocrinologic and Metabolic Advisory Committee**

Food and Drug Administration  
Center for Drug Evaluation and Research  
Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda MD

**Pravachol® NDA 21-198, Pravastatin sodium, 10mg, Bristol- Myers Squibb**

**8:00 Call to Order, Introductions**

Eric Brass, M.D., Chair

**Conflict of Interest Statement**

Sandra Titus, Ph.D., Executive Secretary, PDAC

**Introduction to the Issues**

David Orloff, M.D., Deputy director, DMEDP

**8:15 Bristol-Myers Squibb Presentation**

**9:45 Break**

**10:15 FDA Presentation**

**Medical Review and Introduction**

Mary H. Parks, M.D., Medical Officer, DMEDP

**Use Trials**

Daiva Shetty, M.D., Medical Officer, DOTCDP

**Safety Concerns: Drug Interactions**

Jim Wei, Ph.D., OCPB

**Label Comprehension**

Karen Lechter, Ph.D., DDMAC

**Summary**

Linda Katz, M.D., MPH, Associate Director, DOTCDP

**12:00 Lunch**

**1:00 Charge to Committee**

Linda Katz, M.D., MPH, Associate Director, DOTCDP

**1:15 Discussion and Questions**

**Break**

**4:30 Adjourn**

